

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING )  
PHARMACY, INC. PRODUCTS LIABILITY )  
LITIGATION )  
\_\_\_\_\_ )

MDL No. 2419  
Dkt. No 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO: )

All Cases )  
\_\_\_\_\_ )

**The Tennessee Clinic and Health Care Provider Defendants’  
Memorandum in Support of Proposed Plaintiff Profile Form  
and Joinder in Saint Thomas’s Records Release Proposal**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively “the Tennessee Defendants”) file this memorandum in support of their proposed Plaintiff Profile Form.

The Tennessee Defendants attach their proposed Plaintiff Profile Form as Exhibit A to this brief and request entry of it (or a form of similar substance) as the Plaintiff Profile Form to be used for selection of bellwether candidates.

Additionally, the Tennessee Defendants join Saint Thomas<sup>1</sup> in requesting that the Court adopt Saint Thomas’s proposed records releases.

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<sup>1</sup> “Saint Thomas” includes St. Thomas West Hospital f/k/a St. Thomas Hospital, Saint Thomas Health, and Saint Thomas Network.

## 1. Parties

The “Tennessee Defendants” are defendants named in various combinations in dozens of lawsuits pending in the MDL.

The instant brief is filed on behalf of Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively “the Tennessee Defendants”). The same undersigned counsel represents all the aforementioned “Tennessee Defendants” and, as a matter of economy, files a single brief.

For the Court’s convenience, the defendants named in cases from Tennessee are identified below:

### STOPNC, Howell Allen, Dr. Culclasure, Ms. Schamberg, and Saint Thomas

- Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”) is an ambulatory surgery center in Nashville, Tennessee where New England Compounding Center (“NECC”) methylprednisolone acetate (“MPA”) was administered to plaintiff patients.
- Howell Allen Clinic is a group of neurosurgeons and a one-half owner of STOPNC. Howell Allen Clinic employed John Culclasure, MD (“Dr. Culclasure”) and Debra Schamberg, RN (“Ms. Schamberg”).
- Dr. Culclasure is an anesthesiologist. He was the medical director at STOPNC. He administered the NECC MPA to many of the plaintiff patients at STOPNC. He also participated in the decision to buy MPA from NECC.
- Ms. Schamberg is a nurse and the facility director of STOPNC. She participated in the decision to buy MPA from NECC.
- Saint Thomas is a one-half owner of STOPNC. STOPNC is located on or near the Saint Thomas Hospital campus.<sup>2</sup>

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<sup>2</sup> Saint Thomas is represented by different counsel than these Tennessee Defendants and is expected to file its own brief on these issues.

SSC, Dr. Lister, and Dr. Lister's Practice

- Specialty Surgery Center ("SSC") is an ambulatory surgery center in Crossville, Tennessee, where NECC MPA was administered to plaintiff patients.
- Kenneth Lister, MD ("Dr. Lister") is an anesthesiologist. He administered the NECC MPA to plaintiff patients at SSC and participated in the decision to buy MPA from NECC.
- Kenneth Lister, MD, PC ("Dr. Lister's Practice") is Dr. Lister's practice entity.

**2. Procedural Background for this Brief**

On November 25, 2013, Saint Thomas filed a proposed Plaintiff Fact Sheet to be used to obtain basic information and health history from the plaintiffs as part of the bellwether selection process.<sup>3</sup> The Tennessee Defendants joined in Saint Thomas's pleading proposing use of the fact sheet.<sup>4</sup>

On the same day, the Plaintiffs' Steering Committee ("PSC") filed what, in essence, was a competing proposal to the Saint Thomas proposal, requesting that the Court adopt the "PITWD Addendum" used in NECC's bankruptcy case<sup>5</sup> as a "Plaintiff Profile Form."<sup>6</sup> The PSC argued that the Court should adopt the "PITWD Addendum," a 3½-page form that personal injury claimants were required to file with their proofs of claim in the bankruptcy court, and use that form as the first round of discovery for selection of the bellwether candidate pool.<sup>7</sup>

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<sup>3</sup> [Dkt. 592, Ex. 4].

<sup>4</sup> [Dkt. 597].

<sup>5</sup> Case No. 12-19882 (Bank. D. Mass.). The "PITWD Addendum" can be found at Dkt. 582, Ex. B, in the bankruptcy court record.

<sup>6</sup> [Dkt. 591].

<sup>7</sup> [Dkt. 591].

At the December 13, 2013, status conference, Judge Saylor discussed these competing proposals. Judge Saylor noted that he intended to refer the matter to this Court.<sup>8</sup> In doing so, he offered some guidance to the parties as they embarked on the meet and confer process, stating a desire that “some reasonably detailed fact sheet with relevant information should be produced” that “gives defendants sufficiently substantial information that they can evaluate cases, among other things, for bellwether purposes and that plaintiffs not control which cases discovery occurs in.”<sup>9</sup>

On December 22, 2013, Judge Saylor formally referred resolution of these competing proposals to Magistrate Judge Boal.<sup>10</sup>

On January 7, 2014, this Court entered a scheduling order requiring the parties to (1) meet and confer regarding the profile form by January 17, 2014, (2) file competing proposals by January 24, 2014, (3) file responses to the proposals by January 31, 2014, and (4) be prepared to discuss any remaining areas of dispute at a hearing on February 6, 2014.<sup>11</sup>

In accordance with that order, the parties met and conferred multiple times and exchanged several draft profile forms. To date, the process has been productive, with both sides demonstrating a willingness to negotiate in the spirit of compromise. Notwithstanding these efforts, while negotiation continues, areas of disagreement remain.

With this memorandum, the Tennessee Defendants file their proposed “Plaintiff Profile Form,” which they intend to be used in this litigation as described below.

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<sup>8</sup> See page 75 of the transcript from the 12-13-13 status conference.

<sup>9</sup> Page 59 of the transcript from the 12-13-13 status conference.

<sup>10</sup> [Dkt. 722].

<sup>11</sup> [Dkt. 748].

Additionally, this memorandum sets forth some areas of disagreement about the content of the form as they currently exist.

**3. Present Posture of the Tennessee Defendants' Proposed Plaintiff Profile Form**

While the parties intend to continue to negotiate the contents of the profile form up to the February 6, 2014, hearing, and hope to further narrow the areas of dispute, the proposed form attached as Exhibit A is a reasonable and even-handed approach to this first round of discovery for bellwether selection purposes. It is appropriate for entry now, as-is.

The proposed profile form reflects numerous concessions, multiple rounds of edits to simplify the form, and hours of internal and external discussions about the form and its contents. Illustrating the process, the Tennessee Defendants' proposed profile form is at least five pages shorter than the original defense proposal.

As further evidence of the Tennessee Defendants' willingness to "come to the middle" in response to the various concerns raised by the PSC, the Tennessee Defendants have made many specific concessions and changes, including:

1. Removing 18 of the 21 requests for documents.<sup>12</sup>
2. Removing the item requesting that the plaintiffs describe their job duties.<sup>13</sup>
3. Placing time limits on virtually all questions.<sup>14</sup>
4. Making various wording changes both at the PSC's request and after review and re-review of form to make questions easier to understand and more precise (and, thus, easier for the plaintiffs to answer).
5. Adding charts to allow the plaintiffs to more easily and efficiently provide background demographical and health information.<sup>15</sup>

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<sup>12</sup> See Exhibit A, page 15.

<sup>13</sup> See Exhibit A, ¶ 6.

<sup>14</sup> See, e.g., Exhibit A, ¶ 10.

6. Adding “do not know” options to multiple questions, at the PSC’s request.<sup>16</sup>
7. Modifying the request for Medicare Number to avoid disclosure of sensitive personal information.<sup>17</sup>
8. Removing the request for information regarding absences from work of greater than 30 days.
9. Modifying the questions about lost wages claim to make them less burdensome.<sup>18</sup>
10. Modifying the questions about disability benefits to make them less invasive and more focused in timeframe.<sup>19</sup>
11. Modifying the request for information about previous lawsuits to make it less invasive and more specific.<sup>20</sup>
12. Removing the request for addresses in various questions, lessening the burden on the plaintiffs.<sup>21</sup>
13. Removing the item requesting identification and information regarding family members with history of comorbidities.<sup>22</sup>
14. Removing several specific items in the requests for family medical history and personal medical history.<sup>23</sup>
15. Removing the item asking plaintiffs to identify witnesses.
16. Modifying the question asking for information on tobacco use to make it less invasive.<sup>24</sup>
17. Modifying the question regarding alcohol use to make is less invasive.<sup>25</sup>
18. Modifying the question regarding drug use to make it less invasive.<sup>26</sup>

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<sup>15</sup> See, e.g., Exhibit A, ¶ 40.

<sup>16</sup> See, e.g., Exhibit A, ¶ 5.

<sup>17</sup> See Exhibit A, ¶ 15.

<sup>18</sup> See Exhibit A, ¶¶ 5-7.

<sup>19</sup> See Exhibit A, ¶ 10.

<sup>20</sup> See Exhibit A, ¶ 14.

<sup>21</sup> See Exhibit A, ¶ 28.

<sup>22</sup> See Exhibit A, ¶ 26.

<sup>23</sup> See Exhibit A, ¶¶ 26, 44, 45.

<sup>24</sup> See Exhibit A, ¶ 40.

<sup>25</sup> See Exhibit A, ¶ 41.

The Defendants, in this process, have repeatedly attempted to balance (1) the Defendants' need for relevant, substantial information to select bellwether candidates with (2) the burden and expense of completing the form, all while considering the balance in the setting of the MDL's desire to enhance efficiency. The Tennessee Defendants believe their proposed form balances these interests effectively and fairly.

#### **4. Overview of Framework for Bellwether Process and Role of Profile Form in Process**

First, in order to ensure an effective profile form, the utility of the profile form must be considered in the context of the bellwether process. Here, the specifics of the bellwether process have not yet been set.<sup>27</sup>

The Tennessee Defendants anticipate this profile form will be used to assess whether a plaintiff is appropriate for inclusion in the initial bellwether candidate pool. Once selected for the bellwether candidate pool, the parties will then conduct individual discovery of the cases in the bellwether candidate pool.<sup>28</sup> After individual discovery, the parties will propose bellwether trial cases. After bellwether trial cases are selected, they will be tried.

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<sup>26</sup> See Exhibit A, ¶ 42.

<sup>27</sup> Judge Saylor has not ordered the protocol for bellwether selection. If the process Judge Saylor adopts varies materially from that described herein and generally used, it may be necessary to revise the profile form or adapt future discovery accordingly.

<sup>28</sup> The Tennessee Defendants agreed to eliminate many questions from Saint Thomas's original proposed plaintiff fact sheet that seek discoverable information with the understanding that the information sought by those questions will be provided at the individual case discovery stage for those cases being considered for bellwethers.

This process is consistent with the guideposts the Honorable Eldon E. Fallon<sup>29</sup> describes in his article, *Bellwether Trials in Multidistrict Litigation*.<sup>30</sup>

1. First, catalogue the entire universe of cases, and divide them into distinct, easily ascertainable categories of cases.
2. Second, select a manageable pool of cases that reflects the various categories of cases and contains cases that are amenable to trial in the MDL. Proceed with case-specific discovery in these cases.
3. Third, the court and attorneys collaborate near the end of case-specific discovery to select a pre-determined number of individual cases within the sample and set them for trial.<sup>31</sup>

The Tennessee Defendants intend their proposed form to be used in assisting the parties in moving from Judge Fallon's step one to step two. The form is intended to allow the parties to "have some knowledge about the individual cases in the MDL" via "limited case-specific discovery."<sup>32</sup>

As Judge Fallon explained, without representative bellwethers, "the transferee court and the attorneys risk trying an anomalous case, thereby wasting substantial amounts of both time and money."<sup>33</sup> Thus, the process must have a sufficient exchange of meaningful information prior to bellwether selection to ensure the selection of representative cases.

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<sup>29</sup> During his tenure as a federal district court judge for the Eastern District of Louisiana, Judge Fallon has presided (or is presiding) over the Propulsid MDL, MDL No. 1355, the Vioxx MDL, MDL No. 1657, and the Chinese Drywall MDL, MDL No. 2407. He has written extensively on how this type litigation should be most effectively managed.

<sup>30</sup> Fallon, *et al.*, *Bellwether Trials in Multidistrict Litigation*, TULANE LAW REV., Vol. 82, p. 2223 (2008) (hereinafter "Fallon, [page number]").

<sup>31</sup> Fallon, 2343.

<sup>32</sup> Fallon, 2344.

<sup>33</sup> Fallon, 2344.



In selecting bellwethers, Judge Fallon encourages the transferee court and the attorneys to “focus on those variables that can be easily identified, are substantially important, and provide clear lines of demarcation – *i.e.*, the major variables.”<sup>34</sup> For instance, in the Vioxx litigation, the variables included (1) type of injury, (2) period of drug ingestion, (3) age of patient, (4) prior health history, and (5) date of injury.<sup>35</sup>

In the instant case, the variables tracked in the proposed profile form include (1) type of injury (*e.g.*, fungal meningitis, death, only emotional injury, stroke, *etc.*)<sup>36</sup>; (2) whether the patient received contaminated MPA<sup>37</sup>; (3) underlying health of the individual (*e.g.*, personal medical history, family medical history, identification of treating providers, *etc.*)<sup>38</sup>; (4) nature and extent of damages (*e.g.*, employment information, treatment for injury related to medication, consortium claim information, *etc.*); and (5) state where the injury occurred<sup>39</sup>.

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<sup>34</sup> Fallon, 2345.

<sup>35</sup> Fallon, 2345.

<sup>36</sup> The injury spectrum for these cases runs the gambit from death to “fear of illness” claims with no physical injury. The parties will need to aggregate the number of plaintiffs claiming each type of injury to determine what types of injuries are most appropriate for bellwethers. The parties will also need to consider whether an individual case has unique causation issues that may disqualify it as a bellwether trial candidate, as may be the case with some plaintiffs who suffered stroke.

<sup>37</sup> The majority of plaintiffs complain of injuries arising from their receipt of NECC MPA. Those plaintiffs who claim injuries arising from other medications will present unique causation issues and will probably not be representative.

<sup>38</sup> For example, a 30-year-old patient in relatively good health who contracted fungal meningitis will have a much different claim for damages than an 80-year-old patient with various underlying health issues. Neither may be representative of the plaintiffs as a whole.

<sup>39</sup> Each health care facility defendant will have unique factual and legal issues that will need to be resolved. As it appears that NECC and the Affiliated Defendants have settled, the proof presented will likely center on whether it was a violation of the professional standard of care to purchase from NECC. Therefore, the parties (and the Court) will need to consider the defendants involved in a given case when selecting bellwethers.

After limited case-specific discovery via the profile form, a pool of bellwether trial candidates should be selected from the entire universe of cases. This is done most effectively, per Judge Fallon, by having the *attorneys* select bellwether trial candidates, with judicial intervention if necessary.<sup>40</sup>

Thus, here, the profile form, serving as the initial round of case-specific discovery, must, at a minimum, provide sufficient information for the parties to evaluate the cases in order to determine appropriate bellwether candidates.<sup>41</sup> To do so, the form must elicit “case-specific” information appropriate for bellwether selection, focusing on the variables specific to this MDL.<sup>42</sup>

The Tennessee Defendants’ proposed form serves these purposes, while imposing the least burden possible on plaintiffs in (1) time and expense necessary to complete the form (2) and ease with which it can be completed.<sup>43</sup>

## **5. Areas of Dispute**

First, in determining whether a question should be included in the profile form, common sense suggests a two-part analysis:

1. Is the information requested relevant to the plaintiff’s baseline or damages claimed, or to other variables identified above?
2. How much of that information is necessary at this stage when balanced against the burden of providing the information?

Most of the areas of dispute between the Tennessee Defendants and the PSC concern the second question.

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<sup>40</sup> Fallon, 2348-51.

<sup>41</sup> As Judge Saylor explained at page 59 of the transcript from the 12-13-13 status conference.

<sup>42</sup> Judge Fallon recommends identification of 4-5 variables.

<sup>43</sup> MDLs are increasingly turning to questionnaires as a more efficient way of obtaining discovery from individual plaintiffs. See MANUAL FOR COMPLEX LITIGATION, § 22.83, p. 438. Efficiency is the aim, of course, of multi-district litigation. See 28 USC § 1407.

**a. Timeframe**

As the Court may be aware from reading prior briefing, the parties disagree as to whether many of the historical questions should span ten years or five years.<sup>44</sup>

Ten years is the more appropriate timeframe, given the factors and variables discussed above.

First, ten years of information is necessary to appreciate and analyze the full picture of a plaintiff's baseline. Three or five years is simply too small a sample to ascertain whether a plaintiff's medical or work history is representative of the plaintiff's life as a whole. It is necessary to evaluate a plaintiff's underlying health condition and income information, in particular, on a "trending" basis. Was the plaintiff getting progressively better before the alleged injury? Was the plaintiff progressively worsening before the alleged injury? This is especially important in this setting, where many of the plaintiffs have chronic underlying health conditions, including chronic pain.

Second, even assuming the PSC appropriately believes that ten years of information at this point in the process is "too much," efficiency is served by simply extending the timeframe to the reasonable ten year limit.

After the bellwether candidate pool is selected, individual discovery will commence. "This process should not be any different than the discovery phase of any non-MDL case."<sup>45</sup>

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<sup>44</sup> In some instances, the PSC has suggested a three-year timeframe.

<sup>45</sup> Fallon, 2351.

Information spanning ten years is certainly *discoverable*. It is more economical, for all parties involved, to simply provide the information one time, rather than having to seek five more years of information at a separate second stage. Here, the potential yield of information important to the bellwether candidate selection process outweighs the minimal burden on a plaintiff in extending response to the inquiry five additional years when completing the form.

Third, previous MDLs have consistently used ten years as a fair timeframe. In particular, the Vioxx MDL and Propulsid MDL, which Judge Fallon uses as models in his article, used a ten-year timeframe for historical information.<sup>46</sup>

#### **b. Other Disagreements**

Other specific areas of disagreement include:

- (1) *Whether the profile form should include a request for detailed family history of auto-immune disorder*

While the Tennessee Defendants do believe this is important information for purposes of bellwether candidate selection given the issues in this particular MDL<sup>47</sup>, the Tennessee Defendants have removed the detailed question about family history of auto-immune disease at this stage, with the expectation this will be explored in individual case discovery.

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<sup>46</sup> Attached as Exhibit B are plaintiff profile forms and fact sheets from other MDLs that used, in most instances, ten years as the timeframe for historical information.

<sup>47</sup> Thousands of patients were exposed, but only a small percentage became sick. Logically, an immuno-compromised person reacts more poorly to pathogens. Thus, some may posit, those with weak underlying immune systems did not react to the introduction of the contaminated steroid as the "typical" patient may and required more intense treatment after infection. See Master Compl., ¶¶ 57, 59; see generally Kainer, *et al.*, *Fungal Infections Associated with Contaminated Methylprednisolone in Tennessee*, NEJM, Nov. 7, 2012; Master Compl., ¶¶ 57, 59.

*(2) Whether tobacco, alcohol, and drug use should be broadly inquired into*

The Tennessee Defendants believe that underlying tobacco, alcohol, and drug use is relevant to evaluate the representativeness of the plaintiff. The Tennessee Defendants, in response to the PSC's stated concerns, have modified the question to make it less invasive for those with only minimal tobacco, alcohol, or drug use.

*(3) Whether the profile form should include document requests*

The Tennessee Defendants have eliminated all document requests except those fundamental to obtaining records and evaluating the variables discussed above.

*(4) Various disagreements about wording*

As of the last meet and confer, other areas of disagreement included various requested wording changes. The Tennessee Defendants hope that their current proposed profile form resolves most of those disagreements, but the parties have not yet had opportunity to meet and confer regarding the most recent version of the attached form.

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The Tennessee Defendants recognize that additional disagreements may still arise. They will identify and discuss those areas of disagreement in their response brief due January 31, 2014.

## 6. Conclusion

The Tennessee Defendants outline above the numerous concessions made in developing the attached proposed profile form. The attached proposed profile form serves to effectuate efficient exchange of information with a level of intrusiveness and burden matching the necessity of the information. The Tennessee Defendants, while recognizing that the “meet and confer” process may continue, respectfully request that this honorable Court enter their proposed form or a form covering similar information. In addition, these Tennessee Defendants request that the Court approve the records releases proposed by Saint Thomas.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

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## **CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 24th day of January, 2014.

/s/ Chris J. Tardio

**Chris J. Tardio**